IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

BRENDA PARRISH, INDIVIDUALLY AND AS ADMINISTRATRIX OF THE ESTATE OF KYLE J. PARRISH Plaintiff vs. MEDTRONIC USA, INC., et al. Defendants	)	CASE NO. 1:19-CV-02995 JUDGE JAMES S. GWIN **PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM, AND ALTERNATIVE MOTION FOR LEAVE TO AMEND COMPLAINT**

Now comes Plaintiff, by and through undersigned counsel, and hereby submits the following as her Response To Defendants' Motion To Dismiss For Failure To State A Claim And Motion For Leave To Amend Complaint. Defendants argue that Plaintiff's claims should be dismissed as they are preempted by federal law insofar as the claims seek to apply requirements which is different from, or in addition to, any requirement applicable under 21 U.S.C. §360k(a) governing medical devices. However, federal preemption is not an absolute bar to the pursuit of state tort claims against a manufacturer where those tort claims are "parallel" to the requirements imposed by the

Food and Drug Administration. Plaintiff's Complaint does articulate a plausible set of facts which, if true, constitute a parallel claim, and thus survives preemption.

Assuming the Court is not in agreement that the Plaintiff has met the pleading standard articulated in *Iqbal* and *Twombly*, Plaintiff respectfully requests that the Court grant her leave to amend the Complaint pursuant to Fed. R.Civ.P. 15(a)(2). Defendants do not contend that Plaintiff's complaint as originally filed in the Common Pleas Court of Cuyahoga County, Ohio, fails to meet the pleading standards under Ohio law, which has not adopted the more demanding pleading standards set out in *Iqbal* and *Twombly*. Following removal to this Court by Defendants, fairness and substantial justice would not be served to weigh the sufficiency of the Complaint based on a disparate federal standard which the Plaintiff did not originally set out to meet. Plaintiff would be severely prejudiced to now dismiss the Complaint without affording Plaintiff an opportunity to first amend the Complaint to comply with federal pleading standards under *Iqbal* and *Twombly*.

For these reasons, Plaintiff respectfully requests that the Court deny Defendant's Motion to Dismiss, as the Complaint has sufficiently plead a parallel claim and thus is not preempted. Should the Court disagree and find Defendants' motion well taken, Plaintiff respectfully requests leave to amend the original state court Complaint to comply with the pleading standards under federal law. Plaintiff's reasoning is more fully stated in the below Brief in Opposition

BRIEF IN OPPOSITION

1. SUMMARY OF LAW

I. Preemption and Parallel Claims

"Except as provided in subsection (b) […], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-- (1) **which is different from, or in addition to, any requirement applicable under this chapter to the device**, […]." 21 U.S.C. § 360k(a)(1), emph. added. Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements. *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 322, 128 S. Ct. 999, 1007, 169 L.Ed.2d 892, 902 (2008), citing *Medtronic v. Lohr*, 518 U.S., at 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996).

In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "genuinely equivalent." *McMullen v. Medtronic, Inc.,* 421 F.3d 482, 489 (7th Cir. 2005), citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 453, 125 S. Ct. 1788, 1804, 161 L. Ed. 2d 687 (2005) (emphasis in original). State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law. *Id.* at 489. To survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding federal requirement. *Bates*, supra at 454.

Courts have held that "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for

violating the FDCA—that is, **when the state claim would not exist if the FDCA did not exist**. *Kubicki on behalf of Kubicki v. Medtronic, Inc.,* 293 F. Supp. 3d 129, 186 (D.D.C. 2018). Where misrepresentation claims are based on independent state law duties that would apply to a seller of a product not subject to any federal regulations who engaged in similar alleged misconduct, they are not impliedly preempted. *Schouest v. Medtronic, Inc.,* 13 F. Supp. 3d 692, 705 (S.D. Tex. 2014), citing *Houston v. Medtronic, Inc.,* 957 F.Supp.2d at 1179 (holding that state fraud-based claims that include off-label promotion allegations are not impliedly preempted under Buckman "because they are moored in traditional state common law that exists independently from the FDCA"); see also *Eidson v. Medtronic, Inc.,* 981 F.Supp.2d at 885, 2013 WL 5533081, at *11 (finding that fraud claims based on off-label promotion escape preemption because such claims "are based on state common law tort duties that exist independently from the FDCA and not solely by virtue of the FDCA").

II. Ohio's Pleading Standards and Leave to Amend

"Since the United States Supreme Court decided *Bell Atlantic v. Twombly*, the Ohio Supreme Court has not adopted the 'plausibility standard' set forth in *Twombly*, nor has it cited to Twombly or even mentioned *Twombly*. Indeed, since *Twombly* was released, the Ohio Supreme Court has continued to reference and apply the long-established 'no set of facts' pleading standard in the context of a motion to dismiss." *Tuleta v. Med. Mut. of Ohio*, 2014-Ohio-396, ¶ 23, 6 N.E.3d 106, 113, citing *Rayess v. Edn. Comm. for Foreign Med. Graduates*, 134 Ohio St.3d 509, 2012-Ohio-5676, 983 N.E.2d 1267, ¶ 18; See also *State ex rel. Kerr v. Collier*, 2020-Ohio-457, 2020 WL 717417 (Oh. S.Ct., Feb. 13, 2020) ("Dismissal of a prohibition complaint under Civ.R. 12(B)(6) is appropriate "if,

after presuming the truth of all factual allegations of the complaint and making all reasonable inferences in [the relator's] favor, it appears beyond doubt that **he can prove no set of facts** entitling him to the requested extraordinary writ of prohibition.") emph. added.

"In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. **The court should freely give leave when justice so requires**." Fed. R. Civ. P. 15(a)(2), emph. added. Where a complaint fails to plead sufficient facts to state a claim, the plaintiff may seek leave to amend the deficient complaint. It is within the sound discretion of the district court to grant or deny leave to amend, and the district court has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party. *Iqbal v. Ashcroft*, 574 F.3d 820, 822 (2d Cir. 2009), on remand from *Ashcroft v. Iqbal*, 556 U.S. 662, 687, 129 S. Ct. 1937, 1954, 173 L. Ed. 2d 868 (2009) ("The Court of Appeals should decide in the first instance whether to remand to the District Court so that respondent can seek leave to amend his deficient complaint."), citing *McCarthy v. Dun & Bradstreet Corp.,* 482 F.3d 184, 200 (2d Cir.2007).

2. ARGUMENT AND ANALYSIS

I. Plaintiff's Claims Against Medtronic and Heartware For Negligence and Strict Liability Are Parallel Claims and Thus Not Preempted.

Defendants claim that Plaintiff's claims are preempted by federal law pursuant to the Food, Drug, and Cosmetic Act and the regulations of the Food and Drug Administration. Defendants argue this Court should rely on *Riegel* when determining whether common law claims are available to Plaintiffs in products liability suits concerning Class III

medical devices which have received Premarket Approval ("PMA") from the FDA. As Defendants correctly state, the *Riegel* court determined:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> ***1. which is different from, or in addition to, any requirement applicable under this chapter to the device, and***
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. § 360k(a)."

Riegel v. Medtronic, Inc., 552 U.S. 312, 316, 128 S. Ct. 999, 1003, 169 L.Ed.2d 892, 898 (2008) (emph. added).

However, as Defendants correctly recognized in their Motion to Dismiss, *Riegel* carved out a narrow exception to express preemption for "parallel claims:" state common law claims that are "premised on a violation of FDA regulations" and thus 'parallel,' rather than add to, federal requirements. 552 U.S. at 330 (citation omitted)." (Defendants Reply in Support, 12). In fact, in a similar case to *Riegel*, the Supreme Court of the United States "disclaimed a conclusion that general federal requirements could never pre-empt, or general state duties never be pre-empted," holding in that case "no pre-emption occurred in the case at hand based on a careful comparison between the state and federal duties at issue." *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 322, 128 S. Ct. 999, 1007, 169 L.Ed.2d 892, 902 (2008).

Although the Supreme Court did affirm the lower court's ruling, it held:

> "State requirements are pre-empted under the MDA ***only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1).***

> ***Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.*** *Lohr,* 518 U.S., at 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700; see also *id.*, at 513, 116 S. Ct. 2240, 135 L. Ed. 2d 700."

Riegel v. Medtronic, Inc., 552 U.S. 312, 330, 128 S. Ct. 999, 1011, 169 L.Ed.2d 892, 906 (2008).

The Plaintiff here is not attempting to expand the requirements imposed by federal law. As in this case, the plaintiff in *Lohr* relied on common law to bring an action for damages when her medical device specifically her pacemaker, stopped working. *Id* at 13. The Supreme Court of the United States ultimately held that she was not barred from recovery because of federal preemption, holding:

> "The Lohrs next suggest that even if "requirements" exist with respect to the manufacturing and labeling of the pacemaker, and even if we can also consider state law to impose a "requirement" under the Act, the state requirement is not pre-empted unless it is "different from, or in addition to," the federal requirement. § 360k(a)(1).
>
> Although the precise contours of their theory of recovery have not yet been defined (the pre-emption issue was decided on the basis of the pleadings), it is clear that the Lohrs' allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. At least these claims, they suggest, can be maintained without being pre-empted by § 360k, and we agree.
>
> ***Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.***
>
> ***Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement.***
>
> While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence

> of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law."

Medtronic, Inc. v. Lohr, 518 U.S. 470, 494-495, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). (emph. added).

The only avenue for Plaintiffs in the case at bar are common law claims. In their Motion to Dismiss, Defendants imply that *Riegel* fully and unequivocally bars common law claims against the manufacturer of a medical device. Defendants analysis of *Riegel* and the issue of preemption is incomplete. The Supreme Court in *Lohr* further held:

> ***"The regulations promulgated by the FDA expressly support the conclusion that § 360k 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." 21 CFR § 808.1(d)(2) (1995); see also § 808.5(b)(1)(i). At this early stage in the litigation, there was no reason for the Court of Appeals to preclude altogether the Lohrs' manufacturing and labeling claims to the extent that they rest on claims that Medtronic negligently failed to comply with duties "equal to, or substantially identical to, requirements imposed" under federal law."***

Medtronic, Inc. v. Lohr, 518 U.S. 470, 496-497, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). (emph. added).

In interpreting both *Riegel* and *Lohr*, it is evident that a parallel claim sounding in common law is not federally preempted. Plaintiff has sufficiently plead parallel claims here, by alleging that the specific Products provided to Plaintiff's Decedent were themselves defective and malfunctioning in a manner consistent with a subsequent recall (Complaint, ¶11-12) and that this malfunction was not disclosed to the FDA in violation of 21 CFR § 360c (Complaint ¶13, originally cited under the Food, Drug and Cosmetics Act § 513(a)). This is not a "fraud on the FDA" claim as Defendants allege, but rather a strict liability manufacturing defect claim, coupled with a fraudulent

misrepresentation which is in fact a violation of the FDCA, but would exist independently in state tort. See *Schouest*, supra at 705. The misrepresentation was that the Products were free of the defects which spurred the subsequent recall, i.e. corrosion of the power connections causing fatal device failure. The "fraud" is not on the FDA, but on the Decedent who relied on the company's misstatements submitted to the FDA as part of the PMA process.

Because Plaintiff's Complaint establishes that her claims are parallel, they are not preempted and thus not subject to dismissal here. Therefore, Defendants' Motion to Dismiss should be denied.

II. Assuming Plaintiff Claims Against Medtronic and Heartware Have Not Been Sufficiently Plead, Plaintiff Should Be Granted Leave To Amend Her Complaint.

As the Plaintiff's Complaint was originally filed within the Cuyahoga County Court of Common Pleas, raising state tort claims, the pleading standard adhered to by Plaintiff was the standard employed by Ohio courts. This standard is, in effect, a "notice pleading" standard, and a complaint may only be dismissed in Ohio where it appears beyond doubt the plaintiff can prove "no set of facts" entitling him or her to relief. *State ex rel. Kerr*, supra at ¶11. Defendants do not allege that the Complaint is deficient under this standard, but rather that the Complaint does not satisfy the federal pleading standards laid out in *Iqbal* and *Twombly*. These standards are more exacting, seeking that the plaintiff cross the line from "conceivable to plausible" in the statement of claims in the complaint. See *Iqbal*, supra at 680.

Fed. Civ.R. 15(a)(2) allows a plaintiff to amend their complaint by seeking leave of the court, and states that leave should be freely given where justice dictates. Fed.

Civ.R. 15(a)(2). Justice does so dictate here, as the pleading standard to which Plaintiff complied in drafting her Complaint was not the standard to which Defendants now seek to hold Plaintiff, having successfully removed the case to this Court. Even the Supreme Court in deciding *Iqbal* determined that the plaintiff should be afforded the opportunity to determine whether they may be granted leave to amend their deficient complaint. *Iqbal*, supra at 687. Granting leave is within the discretion of the District Court, and the Court may deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party. *Iqbal v. Ashcroft*, supra at 822. There is no futility here, as Plaintiff has shown above that her claims – properly pleaded – are parallel claims and thus not subject to preemption. Nor is there bad faith or undue delay, as Plaintiff has raised the issue promptly in response to Defendants' allegations that the Complaint was deficient. Further there is no prejudice to Defendants in permitting amendment, but rather it would be highly prejudicial to Plaintiff to dismiss her claims for a mere procedural fluke which, but for the removal of the case at Defendants' request, would not have arisen.

For these reasons, Plaintiff respectfully requests leave to amend her Complaint should the Court determine that it is in fact deficient under the Federal Rules.

3. CONCLUSION

Defendants are not entitled to dismissal here as Plaintiff has successfully plead a parallel claim and thus avoided preemption under the Food, Drug, and Cosmetics Act. Should the Court find otherwise, Plaintiff respectfully requests leave to amend her Complaint, as leave should be given freely where justice so requires and a dismissal

here for failure to adhere to federal pleading standards retroactive to removal would be highly prejudicial to Plaintiff.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 19, 2020, a copy of the foregoing Response To Defendants' Motion To Dismiss For Failure To State A Claim, And Alternative Motion For Leave To Amend Complaint was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system. All parties not capable of receiving electronic documents will be served by regular U.S. Mail. Parties may access this filing through the Court's electronic filing system.

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